Sub-therapeutic drug formulations

*287. SHRI MANOJ BHATTACHARYA : Will the MINISTER OF HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether Government are aware that many substandard sub-therapeutic drug formulations are available in the market and vast rural market is flooded with this;

(b) if so, whether some effective measures are being planned to prevent marketing of such drug formulations; and

(c) if so, the details thereof ?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THAKUR) : (a) to (c) Government has received some complaints about sub-standard and sub-therapeutic drugs being circulated in the market.

Under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder, State Governments have been empowered to enforce the quality of drugs, including monitoring of manufacture, sale and distribution of drugs. The enforcement of quality control of drugs and pharmaceuticals is regulated by a system of licensing by the State Governments. The drugs control officers randomly draw samples from manufacturers, traders and get their quality validated through their Government labs. State Governments are required to take punitive actions, including launching of prosecution against the manufacturers or distributors who are found dealing in manufacture and sale of drugs of questionable quality, including sub-standard or sub-therapeutic formulations.

In order to combat proliferation of drug formulations, the Central Government issued directions in November, 2000 under Section 33P to all the State Governments to instruct their licensing authorities not to issue licences for any new drug formulation, which includes new combination formulations of such drugs. Corresponding rules (69 & 71) under this Act are also being amended so as to ensure that no State Licensing Authority approves a new drug formulation at their level until such time it has been evaluated and approved by the Drugs Controller General of India. A Notification has already been issued on 19-10-2001 inviting objections and suggestions.

Provision related to Good Manufacturing Practices under Schedule M of the Act are also been upgraded and the amendment will be finally made shortly.

The Central Government has also been advising the State Governments from time to time to provide adequate enforcement machinery; to establish their own State level drug testing facilities to ensure speedy analysis of drugs samples; to adopt cautious approach while approving licences for drug products which are sub-therapeutic, harmful or irrational; surveillance of suspected dealers; implementation of Good Manufacturing Practices (GMPs) are laid under Schedule M by the licensed manufacturers; cooperation of pharmaceuticals industry by regular interaction with them; collection of survey samples under National Survey Quality Evaluation of Drug Programme (NSQED); constitution/reactivation of State Drug Advisory Committee in which various trade and industry association as well as consumer associations should find representation. State Governments are being regularly assisted by providings funds and equipment for their laboratories; and by training of their lab and regulatory staff.

Through the process of screening, manufacture and sale of 72 categories of drugs, including Fixed Dose Combinations (FDCs), have so far been phased out or prohibited.

As far as quality is concerned, as per the information available from the State Licensing Authorities, out of 35570 samples tested during the period 1999-2000, 3666 were reported to be of sub-standard quality.

Disposal of pending cases

† *288. PROF. M. M. AGARWAL : Will the Minister of LAW, JUSTICE AND COMPANY AFFAIRS be pleased to state :

(a) whether Government's attention has been drawn to the news-item captioned, "20 Lakh Mukadme 2005 Tak Niptane Ki Yojana," which appreared in the Rashtriya Sahara, dated 31st May, 2001 ;

(b) if so, the details thereof alongwith Government's reaction thereto; and

(c) the details of the steps taken by Government for quick disposal of the cases pending in different courts in the country ?

THE MINISTER OF LAW, JUSTICE AND COMPANY AFFAIRS (SHRI ARUN JAITLEY) : (a) Yes, Sir.

(b) The news-item captioned "20 Lakh Mukadme 2005 Tak Niptane Ki Yojana" refers to the scheme of 1734 Fast Track Courts by the Eleventh Finance Commission upto 2005, the target of disposal of 20 lakh cases by these courts,

†Original notice of the question was received in Hindi.